

C. Remarks

The claims are 1, 3, 4, 7, 8, 10 and 13-30, with claims 1, 21, 23 and 26-28 being independent. Claim 8 has been cancelled and its subject matter added to each of independent claims 1, 21 and 23. In addition, claims 1, 21, 23 and 28 have each been amended to clarify the invention, and claim 9 has been amended to adjust dependency. In particular, claims 1, 21, 23 and 28 have been amended to remove language from the preamble and to insert language into the claim body which describes the capabilities of the composition claimed, and claim 28 has been amended to set forth the amounts of surfactant and foam stabilizing agent and particular foam stabilizing agent combinations. Applicant submits that support is found throughout the specification and claims as originally filed (see, e.g., claims, specification p. 5, lines 10-14, table 1, table 2) and that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Applicant would like to thank the Examiner, as well as the Examiner's supervisor Sreeni Padmanabhan, for the time and consideration extended during the interview of March 4, 2004. During the course of the interview, the deficiencies of the cited references were discussed; in addition, potential claim amendments which would present specific surfactant and/or foam stabilizing agent blends and/or which would remove language from the preamble to the claim body were discussed. Applicant has now amended the claims in view of the issues discussed. In particular, in each of independent claims 1, 21, 23 and 28, the preamble language regarding the capability of forming a stable foam and the suitability for application to the vaginal and anal areas has been removed to the claim body; in addition, a clause regarding the substrate integrity has been added.

Further, each of claims 1, 21 and 23 has been amended to limit the surfactant to the blend set forth in original claim 9, and claim 28 has been amended to recite amounts of ingredients and to limit the foam stabilizing agent to the exemplified blends.

Claims 26-30 stand rejected under 35 U.S.C. §103(a) as being obvious over Singh (U.S. Patent No. 5,858,371) in view of Fowler (U.S. Patent No. 5,635,469), Pregozen (U.S. Patent No. 5,141,803), and Jorgensen (EP 1 055 424). Applicant respectfully traverses this rejection.

Applicants previously articulated arguments with respect to each of claims 26 and 27 are incorporated by reference herein. Independent claim 28 (“foamable aqueous composition”) is directed to a propellant-free foamable aqueous composition comprising water, a surfactant blend (2% to about 35% by weight) of polysorbate 20, triethanolamine cocoyl glutamate and disodium cocoamphodiacetate, and a foam stabilizing agent blend (0.10% to about 5% by weight) of glycerine, xanthan gum and polyethylene glycol (23 oxyethylene) or propylene glycol and xanthan gum; importantly, the composition is capable of forming a stable foam which does not compromise the integrity of a disposable substrate to which it is applied and which is suitable to be applied to the vaginal or anal area.

While Singh is directed to pharmaceutical compositions used with anorectal and colonic diseases, it fails to render obvious the foamable aqueous composition of claims 28-30. In addition to Singh’s complete failure to give a foaming composition formulation (as noted by the Examiner), Singh provides no guidance whatsoever in terms of the formulation of a stable foam as is critical to the present invention. In fact, Singh fails to appreciate that various foam characteristics can be had at all and therefore provides no

guidance with respect to stable foam formulating considerations. Lending credence to the fact that Singh provides no meaningful disclosure with respect to foams is Singh's apparent equation between foam and spray bases. (See Singh, column 5, line 11.) What is more, Singh fails to disclose or suggest either of the disposable substrate, e.g., bathroom tissue, and the pump dispenser; Singh's disclosure of medicated pads is irrelevant as such are wholly different from the substrate of the present invention. Clearly, Singh alone does not render obvious the invention of claims 28-30.

Fowler does not remedy Singh's deficiencies. Not unlike Singh, Fowler fails to disclose or suggest the disposable substrate, e.g., bathroom tissue, of the present invention; clearly, Fowler's suggested sponge or washcloth is not a disposable substrate as is used in the present invention. While Fowler does describe a foam producing cleansing product containing water, surfactants, etc., Fowler fails to disclose or suggest a convenient foam producing cleansing product of the type used in the present invention. In pertinent part, Fowler sets forth:

The personal cleansing products of the present invention are useful for cleansing the skin or hair. Typically, a suitable amount of the cleansing composition is directly applied as a foam from the non-aerosol [pump] to the skin or hair to be cleansed. It is preferred to premoisten the skin or hair with water. Alternatively, a suitable amount of the cleansing composition can be applied to the skin or hair to be cleaned via intermediate application to the hands, a washcloth, a sponge, or other application device. It has been found that the compositions of the present [invention] provide their optimal cleansing performance when combined with water during the cleansing process. To complete the cleansing process, the compositions of the instant invention are thoroughly rinsed from the skin or hair with water. (Column 33, line 66, through column 34, line 12.)

It is abundantly clear that the foaming composition of Fowler is not analogous to the stable foam used in the present invention. First, the foam of Fowler is ideally used with water and must be thoroughly rinsed off the skin and hair to complete the cleansing process. The stable foam used in the invention of claims 28-30 need not be combined with water at any point in the application and/or removal processes. Instead, the present invention is intended to provide a convenient solution to the problems associated with conventional products such as that proposed by Fowler. The stable foam of the present invention can be used simply by dispensing the foam onto a piece of bathroom tissue, applying the foam to the vaginal or anal area, i.e., "wiping", and removing any excess foam with the bathroom tissue.

Second, Fowler is concerned only with cleansing hair and skin; hair and skin are very different from the mucosal vaginal and anal areas to which the presently employed stable foam is to be applied. Applicant has now amended claim 28 to remove the phrase "suitable for use as a vaginal or hemorrhoidal wipe" from the preamble; in its place, the clause "wherein the propellant-free foamable aqueous composition is capable of forming a stable foam when dispensed from a propellantless finger actuated mechanical pump dispenser, wherein the stable foam maintains the integrity of a disposable substrate to which it is applied and wherein the stable foam is suitable for application to the vaginal or anal area" has been added to the claim body. Accordingly, such claim language further defines the product set forth in the body of the claim. As such, the clause should be given due consideration. Further, specific formulation considerations must be made when formulating a vaginal or hemorrhoidal wipe product. For instance, particular surfactant

blends can be critical in producing a foam which can suitably be applied to the vaginal or anal area; accordingly, Applicant has now limited the surfactant to the claimed blend of polysorbate 20, triethanolamine cocoyl glutamate and disodium cocoamphodiacetate. Such a blend results in a foam which is stable and which is suitable for vaginal or anal application. As noted by the Examiner, Fowler provides no guidance at all with respect to the particular surfactant blend set forth in claim 28. For all of the above reasons, Fowler whether considered alone or in combination with Singh fails to render the present invention obvious.

Pregozen fails to remedy the deficiencies of Singh and Fowler. As noted in the previous response, Pregozen relates to moistened or impregnated nonwoven substrates. Quite distinctly, the present invention relates to the use of disposable substrates such as bathroom tissue. As outlined in detail at, inter alia, page 5 of the present specification, the integrity of the bathroom tissue or disposable substrate is not compromised, i.e., there is no absorption or impregnation, according to the present invention. While Pregozen may describe the use of disodium cocoamphodiacetate and polysorbate 20 in its disposable hygiene wipes, Pregozen is not in any way directed to the formulation of stable foams nor the dispensation of such stable foams on a disposable substrate. Because Pregozen is completely unrelated to foam products, the combination of Pregozen and Fowler is inappropriate; Pregozen relates to personal hygiene wipes, while Fowler relates to foaming hair and skin cleansers. In any event, Pregozen fails to aid Singh and Fowler in rendering obvious the invention of present claims 28-30.

Finally, Jorgensen does not remedy the deficiencies of the above-discussed cited art. Jorgensen is cited merely for its alleged teaching of triethanolamine cocoyl glutamate as a preferred foaming agent in a foamable skin cleanser. Jorgensen, like Fowler, is directed to a skin cleanser, as opposed to a vaginal or hemorrhoidal agent as in the present invention. In addition, Jorgensen contains no disclosure or suggestion of the application of its foamable skin cleanser to a disposable substrate; likewise, there is no indication that its foamable skin cleanser would be suitable for such a purpose. Clearly, Jorgensen, even in combination with the other cited references, fails to render the present invention obvious.

In sum, no combination of Singh, Fowler, Pregozen and Jorgensen can be said to render the invention of present claims 26-30 obvious. First, Applicant does not believe that one of ordinary skill in this art would combine these references. They relate to different types of products, and at least three of the four cited references have required elements. Singh requires the presence of a flavanoid-containing *Euphorbia prostate* extract as an active ingredient; Fowler necessarily includes a water soluble cationic or nonionic polymer to aid in the deposition of humectants and/or emollients; and Jorgensen requires the inclusion of a salt of acrylates/ C_{10-30} alkyl acrylate crosspolymer or a salt of acrylates polymer as a foam stabilizer. Certainly no combination of such elements renders the present invention obvious.

Second, the cited references fail to disclose or suggest key features of present claims 28-30, namely a stable foam suitable for application to the vaginal or anal area and particular surfactant and foam stabilizing agent blends. The present invention,

quite simply, is directed to the application of a highly aqueous foam on a very low wet strength disposable substrate such as bathroom tissue; the foam is so designed so as to retain its integrity such that it does not moisten the disposable substrate and collapses only when applied to the vaginal or anal area. All of the medicated pads of Singh, sponge and washcloth of Fowler and moistened or impregnated substrates of Pregozen are fundamentally distinguishable from the low wet strength disposable substrates suitable for use in the present invention. In fact, no foam which could be suggested from any combination of the above-discussed references would be suitable for use with the substrates used in the present invention.

Accordingly, Applicant respectfully requests withdrawal of the §103 rejection premised upon the combination of Singh, Fowler, Pregozen and Jorgensen.

Claims 1, 3, 4, 7-10, 13, 17-21 and 23-25 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski (U.S. Patent No. 6,030,931). Claims 8-10 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski and further in view of Pregozen and Jorgensen. Claims 14-16 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski, Pregozen and Jorgensen and further in view of Mohseni (U.S. Patent No. 5,431,906), Evans (U.S. Patent No. 5,837,661) and Wenninger (Int'l Cosmetic Ingredient Dictionary and Handbook). Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being obvious over Singh in view of Vinski. Applicant respectfully traverses these rejections.

Independent claims 1, 21 and 23 are directed to propellant-free foamable aqueous compositions containing (a) water in an amount from about 70% to about 98% by

weight, based on the total weight of the aqueous composition; (b) surfactant in an amount from about 2% to about 35% by weight, based on the total weight of the aqueous composition, wherein the surfactant is a combination of polysorbate 20, triethanolamine-cocoyl glutamate and disodium cocoamphodiacetate; and (c) foam stabilizing agent in an amount from about 0.10% to about 5% by weight, based on the total weight of the aqueous composition, wherein the foam stabilizing agent is selected from the group consisting of natural and synthetic gums, polyalkylene glycols, alkylene polyols and combinations thereof. Independent claim 21 further includes a medicament; independent claim 23 further includes a lubricant, chelating agent, moisturizer, healing agent, fragrance, color or mixture thereof. All three of these independent claims use “consisting essentially of” language. Importantly, each of the compositions is capable of forming a stable foam which does not compromise the integrity of a disposable substrate to which it is applied and which is suitable to be applied to the vaginal or anal area.

The presently claimed invention is distinct from the cited art. First, the foamable aqueous compositions of this invention must be suitable for application to the vaginal or anal area. Contrary to the Examiner’s position, not every combination of water, surfactant and foam stabilizer would be suitable for such application; specific formulation considerations must be made. Vinski, which is directed to a skin cleansing skin product, does not make such considerations.

Second, Vinski necessarily includes two specific foam densifying agents, namely a C₈₋₁₂ acyl lactylate and an ethoxylated glyceride ester. The foamable aqueous compositions of the present invention, which produce what can be described as light,

quick-breaking foams, do not include such densifying agents and, in fact, are closed to the possibility of such an inclusion given the “consisting essentially of” language; instead, the present claims limit the foam stabilizing agent to natural and synthetic gums, polyalkylene glycols, alkylene polyols and combinations thereof. The foam densifying agents are indispensable to the foaming skin cleanser of Vinski as Vinski aims to produce a “rich, luxurious creamy foam” (column 2, lines 16-17). In Examples 9-18 thereof, only foams which comprised the claimed C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester (Examples 15-18) were deemed completely satisfactory; examples which merely employed an amphoteric surfactant or an anionic surfactant or a combination of the two were deemed deficient in at least some respect. From the disclosure of Vinski, it is clear that the combination of C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester materially affects the overall foam characteristics.

None of the cited secondary references remedy the deficiencies of Vinski; none provide any motivation to prepare stable foams suitable for application to the vaginal or anal area, nor do any provide any motivation to alter the composition of Vinski to remove vital components, i.e., C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester, thereof. What is more, Pregozen, Jorgensen and Singh have additional deficiencies as discussed above, and Mohseni, Evans and Wenninger are cited merely to prove the efficacy of PEG 23M and xanthan gum as suitable thickeners.

In sum, no combination of Vinski, Pregozen, Jorgensen, Mohseni, Evans, Wenninger and Singh can be said to render the invention of present claims 1, 3, 4, 7-10, 13-19 and 22-25 obvious. First, Applicant believes that there are issues which would

preclude the combination of at least some of these references. For instance, Vinski necessarily requires the presence of C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester as foam densifying agents, while Jorgensen requires the inclusion of a salt of acrylates/C₁₀₋₃₀ alkyl acrylate crosspolymer or a salt of acrylates polymer as a foam stabilizer. Certainly no combination of such elements renders the present invention obvious. Second, the cited references fail to disclose or suggest the invention of present claims 1, 3, 4, 7-10 and 13-25, namely they fail to disclose or suggest a propellant-free foamable aqueous composition which forms a stable foam suitable for vaginal or anal application consisting essentially of the claimed amounts of water, specified surfactants and specified foam stabilizing agents. Accordingly, Applicant respectfully requests withdrawal of the §103 rejections premised upon Vinski, Pregozen, Jorgensen, Mohseni, Evans, Wenninger and Singh alone and/or in combination.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue of the present case is respectfully requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


Attorney for Applicant
Registration No. 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200